Employers and Drugstores Press for PBM Transparency

A Labor Department Advisory Committee Has Recommended Changes

Stephen Barlas

Six years ago, Robert Schenk, who administered drug prescriptions for the Meridian Health Systems employee health plan, started to scratch his head over medication costs. Meridian, a nonprofit that owns and operates six hospitals in northern New Jersey, had hired Express Scripts in hopes that the pharmacy benefit manager (PBM) would reduce the system's spending on drugs for employees, according to a 2013 article in *Fortune* magazine.

Schenk had once owned two small-town drugstores, so he knew some of the arcane practices underlying PBM pricing. He discovered that Express Scripts was charging the Meridian health plan $92.53 for a generic amoxicillin prescription filled at an outside pharmacy. Schenk was able to do something that others in his position could not: figure out the "spread," the difference between what the PBM charges the health plan and what it pays the pharmacy. Most health plans do not have access to the PBM's payment to the pharmacy, so they can't compare the two. But Schenk could determine what Express Scripts was paying Meridian's outpatient pharmacy to fill the same prescription: $26.91. That meant a spread of $65.62 on one bottle of a generic antibiotic.

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PBMs argue that spreads are part of a revenue balancing act. "When evaluating spread pricing, it is important to take into account all drugs, including those that the PBM takes a loss on," says David Whitrap, an Express Scripts spokesman.

It is perfectly legal for a PBM to charge a spread of any size. But the extent of that spread is not disclosed pursuant to a contract, nor is the price per prescription the PBM pays a retailer or its direct-mail pharmacy. "Most PBMs do not disclose to employers either the price that they pay to retail pharmacies or drug acquisition costs for their mail operations, which makes the PBM spread nontransparent to sponsors," explains Patricia M. Danzon, PhD, Celia Moh Professor at the Wharton School of the University of Pennsylvania.

Nor does a PBM disclose the rebates it receives from a drug manufacturer, often as a reward for privileged placement on the PBM formulary—although contracts sometimes guarantee a health plan a specific percentage of that rebate. Then the transparency issue becomes the degree to which the plan can audit the PBM rebates. In certain circumstances, that can be difficult to do. Susan A. Hayes, an accredited health care fraud investigator who is Principal of Pharmacy Outcomes Specialists, has consulted with more than 1,000 plan sponsors. She says the $15,000 to $200,000 cost of audits can be prohibitive for smaller firms. "PBMs make it near impossible to audit both their 'secret agreements' for rebates with pharmaceutical companies and retail network agreements with pharmacy chains," Hayes explains. "If the PBM is acting on behalf of the plan sponsor to negotiate rebates or network arrangements, why keep the rebate agreements secret from the entity you are working for?"

Therein lies the controversy over PBM transparency, or the lack thereof, which appears to be headed for a higher profile because of recommendations from a U.S. Department of Labor (DOL) committee. An upcoming report and recommendations in September 2014 from the DOL's ERISA Advisory Council[1] give new life to efforts by the business community and the retail pharmacy industry to convince the DOL to require more transparency from PBMs. ERISA (the Employee Retirement Income Security Act) is the federal law that covers corporate pension and health care plans. For a decade, employer groups, backed by pharmacy trade organizations, have been trying to convince the DOL to issue regulations requiring PBMs to provide more information about the compensation they receive from pharmaceutical manufacturers and other suppliers.

Under current law, PBMs serving ERISA health plans have to file a Schedule C that includes a Form 5500. The kinds of reportable data include dispensing fees the PBM pays to a pharmacy and payments the PBM makes for ancillary administrative services such as record-keeping, data management, information reporting, formulary management, participant health desk service, benefit education, utilization review, claims adjudication, participant communications, reporting services, website services, prior authorization, clinical programs, and pharmacy audits.

"However, PBMs generally do not currently disclose the specific details of their arrangements with pharmaceutical manufacturers," concedes William Kilberg, a Washington attorney with Gibson, Dunn, & Crutcher, LLP, who represents the Pharmaceutical Care Management Association, the PBM trade group. He adds that it is the retail pharmacy industry, not employer health plans, that is pushing the DOL to ramp up PBM transparency requirements. "They want to obtain information regarding PBMs' arrangements with pharmaceutical manufacturers because they believe it would allow them to obtain better deals from PBMs for their benefit," he argues. "ERISA plans and other consumers would not obtain any benefits from this outcome."

Amanda Beck, Vice President of Public Affairs for the HR Policy Association, which represents human resource officers at Fortune 500 companies, says large corporations are very interested in seeing the DOL continue to investigate, although she notes that PBMs serve an important role in keeping employees healthy and productive. "But the industry is beset with a lack of transparency that is difficult to deal with even for the largest employers," she adds. "Unfortunately, benefit consultants, who are often relied upon to help employers with complex situations, are often aligned with specific PBMs, thereby limiting their independence."

The DOL has been paying more attention to ERISA transparency issues lately, making it more likely the department will move into PBM rule-making. Rules for covered service

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providers (CSPs) to pension plans were upgraded in 2012. These rules go beyond the Schedule C disclosure standards. CSPs must give responsible fiduciaries information they need to assess the reasonableness of total compensation, both direct and indirect, received by the CSP, its affiliates, and/or subcontractors. That compensation must be expressed as a monetary amount, formula, percentage of the covered plan's assets, or per capita charge, or by another reasonable method when compensation cannot be expressed in such terms. CSPs can provide "good faith estimates" when they cannot otherwise describe compensation or cost, but the methodology and assumptions used to prepare such estimates must be explained.

Is a DOL Regulatory Initiative Coming Up?

CSP rule-making in 2012 provided momentum for the DOL to move forward on PBM transparency—hence the hearings held in June 2014 by the ERISA Advisory Council. In September 2014, the ERISA Advisory Council made two recommendations:[1]

- The DOL should consider making Section 408(b)(2) regulations—the 2012 enhanced disclosure rules that cover CSPs—apply to welfare plan arrangements with PBMs. That would deem such arrangements reasonable only if PBMs disclose direct and indirect compensation, including compensation paid among related parties such as subcontractors.
- The DOL should consider issuing guidance to assist plan sponsors in determining whether and how to conduct a PBM audit of direct and indirect compensation.

"In the past, some council recommendations have led to regulatory projects," says Michael Trupo, a DOL spokesman. "The department looks forward to reviewing the council's final reports when they are submitted."

At the council hearings last June, several corporate representatives and the National Community Pharmacists Association (NCPA) pressed for greater PBM transparency. Allison Klausner, Assistant General Counsel on Benefits for Honeywell International Inc., says her company "would support a Department of Labor effort to draft new or modify existing regulations that demand PBMs to provide greater transparency with respect to how PBMs provide their services and with respect to their sources of fees and compensation." And when the council's recommendations were released, B. Douglas Hoey, RPh, MBA, the NCPA's Chief Executive Officer, said: "We commend the ERISA Advisory Council on its action and we are also excited that U.S. Labor Secretary Thomas Perez has indicated his desire to ensure those long-overdue changes are implemented." Pharmacies have argued they are victims of spread pricing.

One could argue that transparency is even more important as PBMs sign deals with drug manufacturers for formulary placement of expensive specialty drugs. Both independent PBMs such as Express Scripts and PBMs owned by insurance companies have announced deals with Gilead Sciences and AbbVie for placement of their hepatitis C drugs. Gilead's Sovaldi and Harvoni cost $84,000 and $94,500 per treatment cycle, respectively. AbbVie's Viekira Pak costs more than $83,000. None of the PBMs or insurers has disclosed what they would be paying per patient, what the rebate structure will be, or what portion of any rebates health plan customers will receive.

Kilberg says that there is enthusiastic competition among PBMs for ERISA health plan business and that the competition assures companies of getting fair pricing and maximum contract transparency, an assertion the Federal Trade Commission (FTC) has backed repeatedly over the past decade. "The FTC has consistently opposed regulatory initiatives that would mandate PBMs to disclose their trade secrets and other proprietary information, such as their arrangements with pharmacies and pharmaceutical manufacturers," he adds. "As the FTC has concluded, there is no reason to believe that mandatory disclosures of PBM-related information will help consumers. In fact, they almost certainly would have the unintended effect of driving up prescription drug prices, further increasing the costs borne by ERISA health care plans."

Transparency Rules for Federal Health Plans

Three PBMs control the lion's share of the market: Express Scripts, CVS/Caremark, and Catamaran. Health plans such as Aetna, Humana, and UnitedHealthcare also own PBMs. Mid-size PBMs include EnvisionRxOptions, MedImpact, and Benecard.

Massive fines paid by PBMs in the past decade, often concerning rebates from drug manufacturers, fuel the concern among health plans and pharmacies that PBMs are not trustworthy. These cases were initiated by federal and state law enforcement officials because federal health plans such as Medicare and Medicaid were involved. Different laws apply to those health plans and the PBMs that serve them compared with employer health plans. At least that has been true to date.

AdvancePCS, which is now part of CVS/Caremark, paid $137.5 million in damages for kickbacks, submission of false claims, and other rebate issues in 2005; the violations predated Caremark's acquisition of AdvancePCS in 2004. "These kinds of rebates and hidden fees disguise the true cost of what we're paying," U.S. Attorney Patrick L. Meehan said at the time. In 2008, Express Scripts paid a $9.5 million fine for drug-switching and for illegally retaining rebates, spread profits, and discounts in cases involving federal health plans, not ERISA health plans.

The difficulty that federally sponsored health plans have had with PBMs probably influenced the inclusion of PBM transparency rules in the Patient Protection and Affordable Care Act (PPACA); those rules apply to federal and state marketplace and Medicare Part D health plans. The Department of Health and Human Services (HHS) requires qualified health plans to provide HHS with the following information:

- The percentage of prescriptions provided through retail and mail pharmacies
- Generic dispensing rates by type of pharmacy
- The aggregate amount and type of rebates, discounts, or price concessions attributable to patient use under the plan
- The aggregate amount of rebates, discounts, or price concessions passed through to plan sponsors
- The aggregate amount of the difference between what a plan pays the PBM and what the PBM pays pharmacies
- The total number of prescriptions dispensed

Even these PPACA transparency rules leave something to be desired from a consumer standpoint. "The limited nature and strong confidentiality protections for these disclosures was

an intentional decision of Congress, following input from the FTC, because of the negative impact such disclosures would have on the marketplace," Kilberg states.

The Centers for Medicare and Medicaid Services has gone further by adopting new transparency rules for Medicare Part D drug plans, many of them run by or through PBMs. The new requirement mandates that Part D plans and their PBMs make available to all contracted pharmacies the reimbursement rates for drugs under maximum allowable cost (MAC) pricing standards. This requirement takes effect for the 2016 contract year.

The Arcane World of PBM Pricing

Knowledge of a basic lexicon is required just to begin deciphering the complex world of PBM pricing. Typically, generic drugs are priced on a MAC basis and brand-name drugs on an average wholesale price (AWP) basis. An AWP is set by a private company, Medi-Span, which takes the drug price manufacturers charge the wholesaler, called wholesale acquisition cost (WAC), and increases it, typically, by 20%. Wholesalers distribute and sell drugs to pharmacies, adding a small margin (roughly 2% to 3%).

Unlike AWP, which is a list price set by third-party database companies, each PBM sets its own MAC reimbursement prices for pharmacies. These PBM-generated MAC lists include the upper limit or maximum amount that a PBM will pay for generic drugs and brand-name drugs for which generic versions are available. There is no standard methodology for deriving MAC lists. Neither plan sponsors nor retail pharmacies are told how products are added or removed from a MAC list or the methodology that determines how the maximum cost is calculated or adjusted. "Essentially, the PBMs reimburse low and charge high with their MAC price lists, pocketing the significant spread between the two prices," says David Balto, former Policy Director of the Office of Policy and Evaluation for the FTC's Bureau of Competition. "Most plans are unaware that multiple MAC lists are being used and have no real concept of how much revenue the PBM retains."

Brand-name manufacturers pay rebates for formulary placement, but those rebates have become much less of a factor in the PBM revenue stream as generic drugs have grown to account for around 80% of prescriptions dispensed. As PBMs have made less money on rebates for brand-name drugs, they have pumped up the spreads they earn on generics.

"Spread pricing" is one of the two methods PBMs use for billing clients. The other is called "transparent pricing." In spread arrangements, PBMs negotiate with drug marketers to get aggressive, low contracted rates for retail and mail-order drugs and invoice their plan-sponsor clients at higher contracted rates, profiting from the difference, or "spread." The spread is kept by the PBM and usually not disclosed to the plan sponsor.

Transparent or "pass-through pricing" arrangements involve a contract in which a PBM charges a client a flat administrative fee per claim or per member, and the client pays the exact purchase price or reimbursement rate for the drug that the PBM has negotiated. However, it is important to define the terms subject to the transparency arrangement. For example, market share rebates or payments the PBM receives from a manufacturer for placing a drug on a formulary may be subject to the transparency arrangement, but fees paid to the PBM for clinical programs might not be.

The FTC Has Opposed PBM Transparency

The FTC has given the PBM industry considerable cover in its efforts to ward off new transparency requirements. In 2009, the FTC strongly objected to a proposed New York statute that would have required PBMs to make substantial disclosures to health plans during contract negotiations and annually thereafter. The FTC noted that "health plans appear able to protect themselves … through arm's-length contracts." The FTC concluded that "[a]llowing competition among PBMs is more likely to yield efficient levels of payment sharing, disclosure, and price than contract terms regulated by government regulation."

"In short," Kilberg argues, "the FTC's longstanding position with respect to each state's proposed PBM disclosure regime has been clear and consistent: Mandated disclosures can lead to tacit collusion, which can lead to higher prices. Far from benefiting ERISA plans and consumers of prescription drugs, it is the consumers, including health-plan participants and beneficiaries, who are the ultimate losers in such a scenario."

The problem with rebates is not so much what the PBM receives, but whether the PBM is transferring to the ERISA plan whatever the contract obligates it to provide (assuming the contract requires some transfer, as most do). Large corporations are much more likely to be able to negotiate access to information about rebates and other payments the PBM receives. And studies have shown that PBMs are transferring about 60% to 80% of rebates to clients. But to ascertain that the PBM is doing what its contract mandates, the company has to be able to audit the PBM. That can be a problem.

Plan sponsors may use a variety of techniques to audit PBMs. These may include a pre-implementation audit, which tests the PBM plan design and financial set-up before it goes into effect; a plan design audit, to ensure plan rules are being followed; and a financial audit, which reviews pharmacy claims-level data to verify that all contractual financial guarantees are met. PBM audits can be effective, but they are limited by a number of factors.

The plan sponsor can only audit those items to which the PBM will allow access under the contract terms. Consequently, for example, in a traditional PBM arrangement, the plan sponsor would not be allowed to audit the "spread" because that is not a financial term that is disclosed to the sponsor as part of the arrangement. Plan sponsors may, however, be able to audit rebates if that was negotiated in the contract. In addition, PBMs generally refuse to allow audits unless they pre-approve the auditor. Consequently, the plan sponsor's choice of auditors is often limited. Finally, PBM audits can be time-consuming and costly, and many plan sponsors have limited resources for this process.

It is true that the drugstore industry and ERISA employers with health plans have somewhat different problems with PBMs. But both are on offense while PBMs are on defense, given the Labor Department's perceived receptivity to new regulations as shown by its expansion of pension-provider transparency, PPACA transparency rules, and Medicare Part D initiatives. All of these changes (except the covered service provider rules) forced PBMs to disclose more than they really wanted to.

REFERENCE

1. ERISA Advisory Council, U.S. Department of Labor. PBM compensation and fee disclosure. November 2014. Available at: http://www.dol.gov/ebsa/publications/2014ACreport1.html. Accessed January 22, 2015. ■